

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Integrating contraceptive services into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China
AUTHORS	Jin, Longmei; Yin, Anxin; Zhang, Xiaohua; Jiang, Hong; Zhou, Lu; Zhou, Xiaoyan; Wang, Xiurui; Qian, Xu

VERSION 1 – REVIEW

REVIEWER	Kate Cheney The University of Sydney
REVIEW RETURNED	16-Nov-2022

GENERAL COMMENTS	<p>Thank you for submitting the study protocol for; Integrating contraceptive service into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China.</p> <p>This is a topical and crucial area of health across disciplines and I am very interested. However, I don't understand the system of 'usual care' in this area, it id different to mine. I don't understand who is doing what (what are the roles). The methods need to be clarified (esp sample size), can a flow diagram or table be used? What data are collected?</p> <p>One question I have is how you will measure pregnancy intention? What tool ...London Measure of Unplanned Pregnancy for example is one.</p> <p>Reading the protocol was a bit challenging but I wanted to read and understand it. There are many comments but I just had many thoughts requiring clarity as I read on.</p> <p>Over all langue improvement is required, it is awkward to read in places and meaning is lost.</p> <p>Under: STRENGTHS AND LIMITATIONS OF THIS STUDY: You write - The study will integrate postpartum contraceptive services into existing perinatal care services in China to improve the availability and access of the service</p> <p>Response; Is it only in one Minhang, Shanghai not all of China this is a study in one area and not necessarily represent all of China I think.?</p> <p>Introduction: Q – Are family planning services and postpartum contraceptive services provided in the same way across China? Who provides the education/counselling and provides LARC if chosen?</p> <p>Sorry but I do not understand what you are trying to say here: At present, with the issuance of the three-child policy in China, the service strategy of postpartum family planning emphasizes the need to protect and preserve women 's reproductive health.</p>
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	<p>Study objectives and hypotheses: you speak about China but this study is based in Shanghai. The aim is a bit unclear...do you: aim to assess the effectiveness of care integrating postpartum conception services into existing perinatal care system in Shanghai, in order to prevent unintended pregnancy among women within one year following childbirth...or something like that? Should the unintended pregnancy be the primary and the others secondary? Methods and Analysis Could you explain usual pregnancy care in Shanghai for the reader. Do women usually book in to the local hospital and have care in a free service, do they all see private Dr, do midwives provide most care. Inclusion criteria – I'm sure there is a better way of saying "With normal intelligence" although understanding women with intellectual disability would be interesting too. What will happen to those women who experience stillbirth or baby in special care nursery? This will be good to capture – are they different in some way...do they miss out on care or is it consistent? You may not be powered to assess this. I had to read all the way to Intervention group to understand what the study involved...could this Can you reference the cluster randomization design you use? What is usual postpartum contraception following child birth...IUD at caesarean birth, implant prior to discharge, POP prescription? Why 42 days post birth...is that a usual follow up appointment – do all women attend? When do most women book-in – what is 'early pregnancy'? I am unclear about what staff are doing what and who they are.</p> <p>Intervention Group Membership might include midwives...are they a health workforce in China? I am unsure what pregnancy school is...is it pregnancy and birth classes? If so does everyone have to attend these? I would move this sentence to the start of the paragraph: during the second and third trimester the intervention aims to stimulate consideration of the postpartum contraceptive....Sample size Are you saying unintended pregnancy one year post partum is the primary outcome, this is difference to what you stated earlier. Sample size This is very hard to read and very long sentence doesn't help. Please revise and clarify Who is "drawing information from medical records and how are these data being linked to the participants questionnaire? Who is undertaking the telephone interviews at 6 month and one year points? Data management How will you link surveys to study number without being identified? Are you using REDCAP or some other platform? While I really like the study, I am very confused by the methods section How will you keep the participants from speaking with friends & family who may be in control sites, also the same question for staff? Is this blinded...not sure it can be but...</p> <p>Some references need editing Fig. 1 Research flow chart but in the manuscript Table 1 is Table 1. Summary of the intervention (Page 7) What data will you be capturing in questionnaire and medical</p>
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	records review?
REVIEWER	Parisa Kaliush University of Utah, Clinical Psychology
REVIEW RETURNED	08-Jan-2023
GENERAL COMMENTS	<p>Peer review for bmjopen-2022-066146 “Integrating contraceptive service into existing perinatal care: Protocol for a community-based cluster randomized controlled trial in Shanghai, China”</p> <p>Reviewer Parisa R. Kaliush, M.S. Clinical psychology PhD candidate University of Utah, Department of Psychology</p> <p>Overview This protocol paper describes a cluster randomized controlled trial designed to examine if integrating a contraceptive intervention into preexisting perinatal care in China would reduce unintended pregnancies during the first postpartum year. Data collection is ongoing; the first participant was recruited on 21 September 2020, and the authors anticipate that they will complete data collection by April 2023. This paper has several strengths, including a succinct and compelling Introduction section and a rigorous, large-scale study design. Overall, this study has potential to make a positive impact on reproductive health among families in Shanghai, China. I would have liked to see a section dedicated to “Anticipated Limitations” because I imagine that this project has presented many challenges that the authors have had to address, such as participant retention and protocol compliance among service providers. The additional comments below are intended to strengthen this paper for possible publication.</p> <ol style="list-style-type: none"> Inclusion Criteria: What do the authors mean by including only pregnant women with “normal intelligence?” Do the participants complete cognitive measures to determine their eligibility? Do the authors mean that the participants must be able to perform at a certain reading level in order to complete questionnaires? It is recommended that the authors clarify this inclusion criteria. Training for Service Providers: The authors describe the training modules and pre-/post-training quizzes that service providers must complete before administering the contraceptive intervention. However, it is unclear whether service providers continue to be monitored for intervention protocol compliance. For instance, does the research team review a percentage of randomly selected intervention visits to ensure that service providers are maintaining protocol compliance? It is recommended that the authors elaborate on this point or identify it as a limitation. Intervention for Service Users: The authors describe that during the 2nd and 3rd trimesters, pregnant women in the intervention group participate in “postpartum contraception courses in pregnancy school.” It would be helpful if the authors elaborated on this component of the intervention. For instance, how many courses are required? How long does each course last? Are the courses in-person or virtual? This additional information would offer insight regarding the feasibility and time-commitment of their contraception intervention. Patient and Public Involvement Statement: It is fascinating to read that the authors determined contraceptive service needs and adjusted their questionnaires based on feedback from a pilot survey

	among 1st-trimester pregnant women and postpartum mothers. Would the authors be willing to add more details to this section about feedback provided by pilot participants? This additional information could strengthen the rigor and impact of this paper.
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Dr. Kate Cheney, The University of Sydney

Response to Reviewer 1 Comments :

1. Comments to the Author:

Thank you for submitting the study protocol for: Integrating contraceptive service into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China. This is a topical and crucial area of health across disciplines and I am very interested. However, I don't understand the system of 'usual care' in this area, it is different to mine. I don't understand who is doing what (what are the roles). The methods need to be clarified (esp sample size), can a flow diagram or table be used? What data are collected?

Response 1:

We appreciate the Reviewer's comments. We have added an introduction of the current perinatal care system of China in "INTRODUCTION" section. In China, women register their pregnancy and have their first antenatal examinations in CHCs within three months. After registration and the first antenatal examination at CHC, they will have regular antenatal examinations in local hospitals before childbirth. Obstetricians and obstetric nurses provide antenatal care. During the second and third trimesters, couples can participate in antenatal classes given by obstetricians and obstetric nurses in the hospitals.

After childbirth, women will stay in hospital for at least 24 hours for observation. Obstetricians, obstetric nurses and neonatologists will provide maternal and neonatal health care and health education during this period. Then, at 3-7 days and 14-28 days after hospital discharge, health staff in CHCs will conduct postpartum home visits to check mothers' and newborns' health status as well as provide health care advice. At 42 days after childbirth, women and their newborns will return to the hospitals where they gave birth for check-ups. They will also be provided with guidance such as postpartum health care, infant feeding, regular vaccination and physical examinations.

In the current perinatal care, the "usual care", women only have the chance to receive postpartum contraceptive advice after childbirth, including two times of postpartum home visits and at the 42-day postpartum outpatient clinic visit. However, the education or counselling on postpartum contraception is limited due to the insufficient capacity of obstetric personnel and limited time to discuss the topic. Please refer to the reply to Question 19, we have clarified sample size calculation in the reply.

We submitted the diagram of the study design as a separate file, now we have included it in the attached file for you to review. Information about data collection was shown in "Data collection" section, and we have made some revisions.

In the baseline survey, we will collect participants' demographic characteristics, obstetric history, contraceptive knowledge, and their need for contraceptive services. At the first postpartum home visit and the 42-day postpartum outpatient clinic visit, we will collect participants' postpartum contraceptive knowledge and their plan for postpartum contraception. At six months and one year after childbirth, we will collect data on the incidence of unintended pregnancy, the utilization rate of LARC, and the rate of induced abortion due to unintended pregnancy.

INTRODUCTION (4th paragraph)

"In China, women register their pregnancy and have their first antenatal examinations in community health centres (CHCs) within three months. After registration at CHC, they will have regular antenatal

examinations and antenatal classes provided by obstetricians and obstetric nurses in local hospitals before childbirth. After childbirth, women will stay in maternity wards for at least 24 hours for observation and receive maternal and neonatal health care. Then, at 3-7 days and 14-28 days after hospital discharge, health staff in CHCs will conduct postpartum home visits to check mothers' and newborns' health status as well as provide health care advice. At 42 days after childbirth, women and their newborns will return to the childbirth hospitals for check-ups by obstetricians. Currently, women only have chances of receiving simple postpartum contraceptive education after childbirth including two to three times of postpartum home visits within one month postpartum, and at the 42-day postpartum outpatient clinic."

2. One question I have is how you will measure pregnancy intention? What tool ...London Measure of Unplanned Pregnancy for example is one.

Response 2:

We appreciate this comment. We will measure pregnancy intention via our self-developed questionnaires, and the pregnancy intentions of participants are self-reported. We will conduct telephone interviews at six months and one year after delivery and ask participants whether they fall pregnant. If a participant gets pregnant, we will ask if this pregnancy is planned or accidental. We will define it as unintended pregnancy if the pregnancy is not planned.

3. Reading the protocol was a bit challenging but I wanted to read and understand it. There are many comments but I just had many thoughts requiring clarity as I read on. Over all language improvement is required, it is awkward to read in places and meaning is lost.

Response 3:

We appreciate this comment and apologize for the language problem. We have asked an English-speaking colleague to assist us in improving the English writing.

4. Under: STRENGTHS AND LIMITATIONS OF THIS STUDY:

You write - The study will integrate postpartum contraceptive services into existing perinatal care services in China to improve the availability and access of the service

Response; Is it only in one Minhang, Shanghai not all of China this is a study in one area and not necessarily represent all of China I think.?

Response 4:

We appreciate this comment. This research will provide evidence for improving the availability and access to the service in China. We have revised the contents as the following. It is true that the study will only include one district of Shanghai, China. We have added this as one of the study limitations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

"1) The study will integrate postpartum contraceptive services into the existing perinatal care system and provide evidence and an example to improve the availability and access to the services in China."

"5) The study will be conducted in one urban district of Shanghai, China, the external validity of the results in other areas might be limited."

5. Introduction:

Q – Are family planning services and postpartum contraceptive services provided in the same way across China? Who provides the education/counselling and provides LARC if chosen?

Response 5:

We appreciate the questions. Family planning services and postpartum contraceptive services are provided in a similar way across China. Health staff in community health centres (CHCs) provide brief

postpartum contraception education during postpartum home visits. Obstetricians in maternity hospitals provide postpartum contraception education/counselling, including LARC at the 42-day postpartum examination.

6. Sorry but I do not understand what you are trying to say here: At present, with the issuance of the three-child policy in China, the service strategy of postpartum family planning emphasizes the need to protect and preserve women 's reproductive health.

Response 6:

We appreciate this comment. With the issuance of the three-child policy in China, now couples are encouraged to have three children, women should understand and practice birth spacing and postpartum contraception. We have revised the sentence in "INTRODUCTION" section.

INTRODUCTION (5th paragraph)

"With China's new policy encouraging couples to have three children²², postpartum contraception is even more critical in promoting the physical and mental recovery of postpartum women, maintaining reasonable birth spacing, improving early childhood development and enhancing family and social harmony."

7. Study objectives and hypotheses:

you speak about China but this study is based in Shanghai.

Response 7:

We appreciate this comment. The existing perinatal care system is very similar across China. Therefore, if the intervention is proved effective in our study, it can be referred across China. However, it is true that our study only includes Shanghai. Therefore, we have revised the sentence to clarify.

Study objectives and hypotheses (1st paragraph)

"This study aims to assess the effectiveness of integrating postpartum conception services into the existing perinatal care system in Shanghai, China, to prevent unintended pregnancy among women within one year after childbirth."

8. The aim is a bit unclear...do you: aim to assess the effectiveness of care integrating postpartum conception services into existing perinatal care system in Shanghai, in order to prevent unintended pregnancy among women within one year following childbirth...or something like that? Should the unintended pregnancy be the primary and the others secondary?

Response 8:

We appreciate the comments. We have revised the sentence accordingly. The primary outcome of this study is the incidence of unintended pregnancy within one year after childbirth. The utilization rate of LARC, rate of induced abortion due to unintended pregnancy, and knowledge of postpartum contraception are secondary outcomes. Specific introductions for outcomes are provided in "Primary outcome" and "Secondary outcomes" sections.

Study objectives and hypotheses (1st paragraph)

"This study aims to assess the effectiveness of integrating postpartum conception services into the existing perinatal care system in Shanghai, China, to prevent unintended pregnancy among women within one year after childbirth."

9. Methods and Analysis

Could you explain usual pregnancy care in Shanghai for the reader. Do women usually book in to the local hospital and have care in a free service, do they all see private Dr, do midwives provide most care.

Response 9:

We appreciate this comment. We have added an introduction of the current perinatal care system of China in “INTRODUCTION” section. Please refer to our reply to Question 1. In China, women register their pregnancy and have their first antenatal examinations in CHCs within three months after pregnancy. After pregnancy registration, they will have antenatal and postnatal health care services provided by childbirth hospitals and CHCs. Some of the services are covered by primary public health programs and the majority of the cost in hospitals can be reimbursed from health insurance. In Shanghai, most women utilize perinatal care in public hospitals. Women can use the service in private hospitals where the cost is much higher than public ones and women need to pay the majority by themselves. Obstetricians, obstetric nurses and midwives of hospitals provide the perinatal care together. Midwives mainly provide intrapartum care during natural delivery.

10. Inclusion criteria – I’m sure there is a better way of saying “With normal intelligence” although understanding women with intellectual disability would be interesting too. What will happen to those women who experience stillbirth or baby in special care nursery? This will be good to capture – are they different in some way...do they miss out on care or is it consistent ? You may not be powered to assess this.

Response 10:

We appreciate this comment. We set the “With normal intelligence” criterion to ensure that participants are able to complete the self-administered questionnaires of our study. In practice, we included all the women who can read and understand Chinese and no one has been excluded due to this criterion so far. We have reworded the criterion as suggested. We excluded women who experienced stillbirth or baby in special care nursery since women might not have interest to communicate postpartum contraception under this circumstance. We have added these two conditions in the exclusion criteria.

METHODS AND ANALYSIS (Inclusion criteria section)

“1)With the ability to read and understand Chinese”

METHODS AND ANALYSIS (Exclusion criteria section)

“2)Stillbirth

3)Baby in special care nursery”

11. I had to read all the way to Intervention group to understand what the study involved...could this

Response 11:

We appreciate this comment. We have revised the “Participants and recruitment” section. Our study involved all 13 communities of Minhang District, Shanghai. Eligible women who register pregnancy in these CHCs and agree to participate in the study will be recruited.

METHODS AND ANALYSIS (Participants and recruitment section, 2nd paragraph)

“All 13 communities in the district will be included in this trial and be randomly assigned to the intervention and control groups. In China, women register their pregnancy in community health centres (CHCs) within three months after pregnancy. They will receive perinatal care in the hospitals they choose to give birth and CHCs until 42 days postpartum. Women who register their pregnancy in CHCs and are eligible for the study will be invited to participate in the study by the health staff in CHCs.”

12. Can you reference the cluster randomization design you use?

Response 12:

We appreciate this comment. We have added the reference of the cluster randomization design.

REFERENCES

“23. He Y, Zhang N, Wang J, et al. Evaluation of two intervention models on contraceptive attitudes and behaviors among nulliparous women in Shanghai, China: a clustered randomized controlled trial. *Reprod Health* 2017;14(1):73. doi: 10.1186/s12978-017-0331-4”

13. What is usual postpartum contraception following child birth...IUD at caesarean birth, implant prior to discharge, POP prescription?

Response 13:

We appreciate this comment. In China, IUD at caesarean birth is seldomly used. It is usually considered after the 42-day postpartum check-up and the reproductive system is recovered. During the childbirth hospitalization, obstetricians remind women to use contraception methods, but actually no detailed advice is provided.

14. Why 42 days post birth...is that a usual follow up appointment – do all woman attend?

When do most women book-in – what is ‘early pregnancy’?

I am unclear about what staff are doing what and who they are.

Response 14:

We appreciate the comments. In China, women register their pregnancy in community health centres (CHCs) within three months after pregnancy, which is called “early pregnancy registration”. We have revised the word into “pregnancy registration” and added an introduction of the current perinatal care system of China in “INTRODUCTION” section. Please refer to our reply to Question 1.

15. Intervention Group

Membership might include midwives...are they a health workforce in China?

Response 15:

We appreciate this comment. In China, midwives mainly provide intrapartum care for natural deliveries. They usually work in the delivery room rather than the outpatient clinic. Therefore, we didn’t include midwives in intervention implementation.

16. I am unsure what pregnancy school is...is it pregnancy and birth classes? If so does everyone have to attend these?

Response 16:

We appreciate this comment. We have revised the word “pregnancy school” into “antenatal classes”. In China, childbirth hospitals set antenatal classes. Some contents of the classes are mandatory for pregnant women and some are voluntary. In this study, our research team prepared the course materials and video of the postpartum contraception class. Participants in the intervention group will be asked to take this class.

METHODS AND ANALYSIS (Intervention group section, 6th paragraph)

“At the second and third trimesters, the intervention aims to stimulate interest in a postpartum contraceptive plan. Participants in the intervention group will take a 45-minute postpartum contraception class given by obstetricians and obstetric nurses in the hospital antenatal classes, which include appropriate methods, common misunderstandings, and recommendations for postpartum contraception. Specifically, when participants have their antenatal examinations,

obstetricians will make an appointment for them to attend this postpartum contraception class. Obstetricians and obstetric nurses will use the same multimedia materials and video prepared by our research team and provide explanations face to face during the contraception class.”

17. I would move this sentence to the start of the paragraph: during the second and third trimester the intervention aims to stimulate consideration of the postpartum contraceptive....

Response 17:

We appreciate this comment. We have moved the sentence as suggested.

METHODS AND ANALYSIS (Intervention group section, 6th paragraph)

“At the second and third trimesters, the intervention aims to stimulate interest in a postpartum contraceptive plan.”

18. Sample size

Are you saying unintended pregnancy one year post partum is the primary outcome, this is difference to what you stated earlier.

Response 18:

We appreciate this comment. Our primary outcome is the incidence of unintended pregnancy within one year after childbirth.

19. Sample size

This is very hard to read and very long sentence doesn't help. Please revise and clarify

Response 19:

We appreciate this comment. We calculated the sample size based on our primary outcome, and then used the sample size to calculate the statistical power for the secondary outcomes. We have made revisions to make it clearer.

METHODS AND ANALYSIS (Sample size and statistical power calculation section, 1st paragraph)

“The estimated incidence of unintended pregnancy within one year postpartum was 10% in the control group²⁶, the expected difference between the intervention group and the control group was 6%²⁷, and the intraclass correlation coefficient (ICC) was 0.0128. A sample size of 1040 pregnant women (80 in each CHC) will be needed at 0.05 significance level and 80% statistical power. Given the 20% anticipated rate of loss to follow-up from recruitment to one year after childbirth, a total of 1300 women (100 in each community health service centre) will be required.”

METHODS AND ANALYSIS (Sample size and statistical power calculation section, 3rd paragraph)

“The estimated LARC utilization rate in the control group was 25% and the expected Odds Ratio was 1.6 between the two groups²⁹. Given the calculated sample size of 80 per cluster based on the primary outcome, the statistical power will be 97.5% for the utilization rate of LARC at 0.05 significance level.”

20. Who is “drawing information from medical records and how are these data being linked to the participants questionnaire?”

Response 20:

Health staff in CHCs will draw medical history information from the Health Information System (HIS) of the CHCs, and obstetricians will draw medical history information from the HIS of the hospitals. Since participants' medical history information is only used by service providers for providing appropriate

individual postpartum contraception methods. This information is not linked to the questionnaires, we have deleted this sentence in “Data collection” section.

21. Who is undertaking the telephone interviews at 6 month and one year points?

Response 21:

Health staff in CHCs will undertake the telephone interviews at 6 months and one year postpartum. We have revised relevant sentences to clarify.

METHODS AND ANALYSIS (Data collection, 5th paragraph)

“At half a year and one year after childbirth, information on participants’ selections of contraceptive methods, their utilization frequency and satisfaction of the chosen contraception, conception condition and abortion experience will be collected via telephone interviews by health staff in CHCs.”

22. Data management

How will you link surveys to study number without being identified? Are you using REDCAP or some other platform?

Response 22:

We will use online questionnaires in this study and all information will be stored in the questionnaire platform and secured with an account and password. We will not collect participants’ identity information, such as names or identification numbers. Unique project identification numbers will be assigned to each participant during recruitment, so it will be anonymised.

23. While I really like the study, I am very confused by the methods section

How will you keep the participants from speaking with friends & family who may be in control sites, also the same question for staff? Is this blinded...not sure it can be but...

Response 23:

We appreciate this comment. We used a community-based cluster randomized controlled trial design to achieve minimal contamination because participants are more likely to communicate with others in the same community. Even if they talk about postpartum contraception with people in control sites, they may not be able to provide professional counselling and advice. Therefore, we believe the contamination problem will be minimum in this study. Service providers and participants in our study will not be blinded to the group allocation due to the nature of the intervention. But the statistician will be blinded for the group allocation.

24. Some references need editing

Response 24:

We appreciate this comment. We have revised the references.

25. Fig. 1 Research flow chart but in the manuscript Table 1 is Table 1. Summary of the intervention (Page 7)

What data will you be capturing in questionnaire and medical records review?

Response 25:

We appreciate this comment. Please refer to our reply to Question 1, we have added the diagram and information on data collection in the reply.

Comments from Reviewers: Reviwer 2

Reviewer 2

Dr. Parisa Kaliush, University of Utah

Response to Reviewer 2 Comments :

Overview: Comments to the Author:

My comments to the authors are attached to this review as a Word doc. Thank you for the opportunity to review this manuscript.

This protocol paper describes a cluster randomized controlled trial designed to examine if integrating a contraceptive intervention into preexisting perinatal care in China would reduce unintended pregnancies during the first postpartum year. Data collection is ongoing; the first participant was recruited on 21 September 2020, and the authors anticipate that they will complete data collection by April 2023. This paper has several strengths, including a succinct and compelling Introduction section and a rigorous, large-scale study design. Overall, this study has potential to make a positive impact on reproductive health among families in Shanghai, China. I would have liked to see a section dedicated to “Anticipated Limitations” because I imagine that this project has presented many challenges that the authors have had to address, such as participant retention and protocol compliance among service providers. The additional comments below are intended to strengthen this paper for possible publication.

Response:

We appreciate the Reviewer’s positive comments. We have added the “Anticipated Limitations” in the last paragraph of “DISCUSSION” section.

DISCUSSION (4th paragraph)

“There are several anticipated limitations of this study. First, the intervention model was designed based on the current perinatal care system in urban areas of Shanghai, China, so it may not be applicable to rural areas. Second, participant retention may be challenging as the follow-up will be about 20 months, i.e., from pregnancy to one year postpartum. To minimize the rate of loss to follow-up, we will implement the intervention in the existing maternal care system, tapping in the usual care to deliver the intervention contents.”

1. Inclusion Criteria: What do the authors mean by including only pregnant women with “normal intelligence?” Do the participants complete cognitive measures to determine their eligibility? Do the authors mean that the participants must be able to perform at a certain reading level in order to complete questionnaires? It is recommended that the authors clarify this inclusion criteria.

Response 1:

We appreciate these comments. We set the “With normal intelligence” criterion to ensure that participants are able to complete the self-administered questionnaires of our study. In practice, we included all the women who can read and understand Chinese and no one has been excluded for this criterion so far. We have revised the phrase as the following.

METHODS AND ANALYSIS (Inclusion criteria section)

“1)With the ability to read and understand Chinese”

2. Training for Service Providers: The authors describe the training modules and pre-/post-training quizzes that service providers must complete before administering the contraceptive intervention. However, it is unclear whether service providers continue to be monitored for intervention protocol

compliance. For instance, does the research team review a percentage of randomly selected intervention visits to ensure that service providers are maintaining protocol compliance? It is recommended that the authors elaborate on this point or identify it as a limitation.

Response 2:

We appreciate this comment. We have adopted multiple approaches to ensure protocol compliance. Project managers and research investigators act as quality controllers and are responsible for monitoring the recruitment process on the sites and making records. Furthermore, each woman needs to sign the intervention confirmation forms after each intervention session. These forms will be checked routinely by the quality controllers. Based on the records and summary of site supervision, we held regular meetings with experts and staff of CHCs and childbirth hospitals to solve the existing problems and ensure the intervention protocol compliance. We have added these monitoring measures in the “Process evaluation” section.

METHODS AND ANALYSIS (Process evaluation section, 1st paragraph)

“The designated project managers and investigators will act as quality controllers, and will be responsible for monitoring the recruitment process on the sites and making records. During the intervention, both service providers and participants in the intervention group will be asked to sign a confirmation form after each face-to-face intervention at pregnancy registration, postpartum hospitalization, postpartum home visits, and 42-day postpartum check-up as an implementation process recording. Key components of the intervention at each stage will be listed on the form, and the participants will confirm whether they received the intervention by signing at the end of the form. The quality controllers will check these forms routinely to ensure the implementation is consistent with the plan. In addition, based on the records and periodical summary of site supervision, we will hold regular meetings with experts and staff of CHCs and childbirth hospitals every two months to solve the existing problems and ensure intervention protocol compliance.”

3. Intervention for Service Users: The authors describe that during the 2nd and 3rd trimesters, pregnant women in the intervention group participate in “postpartum contraception courses in pregnancy school.” It would be helpful if the authors elaborated on this component of the intervention. For instance, how many courses are required? How long does each course last? Are the courses in-person or virtual? This additional information would offer insight regarding the feasibility and time-commitment of their contraception intervention.

Response 3:

We appreciate this comment. We have elaborated on the contraception course intervention. Participants will have one contraception class lasting for 45 minutes during the intervention. The class is in-person and teachers of the antenatal classes will use the same multimedia materials and video prepared by our research team for participants in the intervention group.

METHODS AND ANALYSIS (Intervention group section, 6th paragraph)

“Participants in the intervention group will take a 45-minute postpartum contraception class given by obstetricians and obstetric nurses in the hospital antenatal classes, which include appropriate methods, common misunderstandings, and recommendations for postpartum contraception. Specifically, when participants have their antenatal examinations, obstetricians will make an appointment for them to attend this postpartum contraception class. Obstetricians and obstetric nurses will use the same multimedia materials and video prepared by our research team and provide explanations face to face during the contraception class.”

4. Patient and Public Involvement Statement: It is fascinating to read that the authors determined contraceptive service needs and adjusted their questionnaires based on feedback from a pilot survey among 1st-trimester pregnant women and postpartum mothers. Would the authors be willing to add

more details to this section about feedback provided by pilot participants? This additional information could strengthen the rigor and impact of this paper.

Response 4:

We appreciate this positive comment. We have added more details about feedback provided by pilot participants in the “Patient and Public Involvement statement” section.

METHODS AND ANALYSIS (Patient and Public Involvement statement section, 1st paragraph)

“Furthermore, we conducted a pilot survey among ten pregnant women during the first trimester and ten postpartum women, and improved the questionnaires based on their feedback. All pilot participants have confirmed that the questionnaires were easy to understand without ambiguity or obscurity. Postpartum women suggested adding a satisfaction survey for intervention services to monitor and improve the intervention process. In addition, participants of the pilot survey proposed to add a question collecting the specific contraceptive method recommended by service providers during the counselling.”

VERSION 2 – REVIEW

REVIEWER	Kate Cheney The University of Sydney
REVIEW RETURNED	09-Feb-2023

GENERAL COMMENTS	<p>Thank you for the resubmission of this protocol "Integrating contraceptive services into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China "</p> <p>- I note your responses to reviewer comments and this is a much better version, thank you.</p> <p>- apologies but I am unable to find references 10 -15 **I am unable to verify all the references**</p> <p>Just a question not related to publication bu interest, did you consider including women who had a stillbirth or baby in nursery?</p> <p>There are just some basic publication prep but really just for editorial staff.</p>
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REVIEWER	Parisa Kaliush University of Utah, Clinical Psychology
REVIEW RETURNED	23-Feb-2023

GENERAL COMMENTS	The authors sufficiently addressed my questions and comments from the initial review. Thank you for the opportunity to review a revision of this manuscript.
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VERSION 2 – AUTHOR RESPONSE

Reviewer 1

Dr. Kate Cheney, The University of Sydney

Response to Reviewer 1 Comments :

1. Thank you for the resubmission of this protocol "Integrating contraceptive services into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China "

- I note your responses to reviewer comments and this is a much better version, thank you.

Response 1:

We greatly appreciate the Reviewer's careful review of our work and the positive comments for our revised manuscript.

2. - apologies but I am unable to find references 10 -15 **I am unable to verify all the references**

Response 2:

We appreciate this comment. The references 10-15 were published in Chinese journals. We indicated them as suffixes "[in Chinese]" to each reference in Chinese. We are more than happy to send you the pdf files if you are interested.

3. Just a question not related to publication but interest, did you consider including women who had a stillbirth or baby in nursery?

There are just some basic publication prep but really just for editorial staff.

Response 3:

We appreciate this comment. In this study, we excluded women who experienced stillbirth or baby in special care nursery since women might not have interest to communicate postpartum contraception under this circumstance. We will consider including this population in future research.

Comments from Reviewers: Reviwer 2

Reviewer 2

Dr. Parisa Kaliush, University of Utah

Response to Reviewer 2 Comments :

Overview: Comments to the Author:

The authors sufficiently addressed my questions and comments from the initial review. Thank you for the opportunity to review a revision of this manuscript.

Response:

We greatly appreciate the Reviewer's careful review of our work and the positive comments for our revised manuscript.